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Environmental Protection Agency

40 CFR Part 721

Significant New Use Rules; General Provisions for New Chemical Follow-up; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPTS-50553B; FRL-3504-6]

Significant New Use Rules; General Provisions For New Chemical Follow-Up

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: EPA, under sections 5 and 26(c) of the Toxic Substances Control Act (TSCA), is establishing an expedited process for issuing significant new use rules (SNURs) for certain new chemical substances. The new process will apply to: (1) New chemical substances for which EPA has issued orders under section 5(e) of TSCA, and (2) other new chemical substances for which no section 5(e) orders have been issued, but which may present hazards to human health or the environment if exposures or releases are significantly different from those described in the premanufacture notice (PMN). EPA is also establishing standard language for designating certain significant new uses, recordkeeping, and other requirements.

DATES: In accordance with 40 CFR 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1 p.m.eastern time on August 10, 1989. This rule shall become effective October 10, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 544- 0551.

SUPPLEMENTARY INFORMATION: This rule establishes standardized significant new uses and recordkeeping requirements which can be cited in SNURs applicable to individual substances. The rule also establishes procedures for expedited promulgation of SNURs, and for EPA consideration of requests from interested parties to amend or revoke SNURs.

Public reporting burden for this collection of information is estimated to average 12.2 hours per response for Subpart B, and to average 25.3 hours per response for Subpart C, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 marked "Attention: Desk Officer for EPA."

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604 (a)(2)) authorizes EPA to designate a use of a substance as a significant new use. EPA makes this designation by issuing a SNUR after it has considered all relevant factors, including those listed in section 5(a)(2). Under section 5(a)(1)(B) of TSCA, persons must submit a significant new use notice to EPA at least 90 days before they manufacture, import, or process a substance for a significant new use. Persons subject to a SNUR must follow the same rules and procedures as persons who are required by section 5(a)(1)(A) of TSCA to submit a PMN.

Section 26(c) of TSCA (15 U.S.C. 2625(c)) authorizes EPA to take action under other sections of TSCA with respect to categories of chemical substances.

II. Introduction

A. Summary

This rule amends 40 CFR Part 721 by establishing new Subparts B, C, and D and by amending Subpart A. Other amendments to Subpart A were recently promulgated at 53 FR 28358 (July 27, 1988).

In Subpart A this rule establishes definitions of terms found in Subparts B, C, and D. Some of the terms were proposed in the **Federal Register** of April 22, 1986 (51 FR 15104), and of April 29, 1987 (52 FR 15593); other terms were added in response to comments made on the proposed rules. The new terms were included because they were necessary for the practical functioning of Subparts B, C, and D. None of the new terms modifies the substance of the proposed rules.

Subpart B establishes standard significant new use designations. Each standard significant new use will apply to a specific substance only if it is cited in the SNUR for that specific substance. EPA may designate as significant new uses activities other than those for which standard designations are provided for in Subpart B. When the standard designations contained in Subpart B do not provide an adequate description of a significant new use, EPA will develop an appropriate designation and use it in the SNUR for the specific substance. If EPA expects to use the same language in future SNURs, EPA will amend Subpart B to include the new use designation. The hazard communication provisions contained in Subpart B were proposed on April 22, 1986 (51 FR 15104). All other provisions contained in Subpart B were proposed in the **Federal Register** of April 29, 1987 (52 FR 15594).

Subpart C establishes recordkeeping requirements which will apply for a specific substance only if cited in the SNUR for that specific substance. EPA may designate recordkeeping requirements other than those for which standard designations are provided for in Subpart C. When the standard designations contained in Subpart C do not provide an adequate description of a needed recordkeeping requirement, EPA will develop an appropriate description and place it in the SNUR for the specific substance. If EPA expects to use the same language in future SNURs, EPA will amend Subpart C to include the new recordkeeping requirement. Subpart C was proposed in the **Federal Register** of April 29, 1987 (52 FR 15594).

Subpart D contains expedited procedures for establishing significant new use requirements for certain new substances that have completed PMN review and are regulated by an order issued under section 5(e) of TSCA. Subpart D also contains criteria used to determine whether uses not identified in the PMN of substances which have completed PMN review and have not been the subject of a section 5(e) order will be considered candidates for a SNUR under expedited procedures. In addition, Subpart D contains a procedure through which a person may request limitation or revocation of SNURs which were promulgated under this expedited procedure. Subpart D limits the significant new use designations that may be included in SNURs issued under the expedited procedures for non-section 5(e) substances. Subpart D was proposed in the **Federal Register** of April 29, 1987 (52 FR 15593).

Subpart E was established in the **Federal Register** of February 2, 1988 (53 FR 2845). It contains SNURs for specific chemical substances.

B. Changes From the Proposed Rule

As discussed above, the hazard communication provisions of this final rule were proposed on April 22, 1986, and the remainder of this rule was proposed on April 29, 1987. The following changes have been incorporated in this final rule:

1. The proposed standard significant new use designations and recordkeeping

requirements in Subparts B and C have been modified to be consistent with the standard provisions for section 5(e) consent orders which were developed in a public comment process announced in the **Federal Register** of March 6, 1988.

2. This rule adopts most of the Occupational Safety and Health Administration's (OSHA) hazard communication standard (29 CFR 1910.1200). EPA is not adopting certain parts of OSHA's hazard communication standard because they either are covered in other sections of EPA rules or are not applicable. EPA did not adopt a requirement in OSHA's standard (pertaining to trade secrets) that the identity of the substance must be released to a physician or nurse during a medical emergency. Instead, EPA has required that a person who can provide treatment information when a person has been exposed to the SNUR substance be designated in the material safety data sheet (MSDS) and on the label. EPA received no comment on this issue.

3. On April 29, 1987, EPA had proposed a program under which it would issue immediately effective final SNURs for new chemical substances subject to TSCA section 5(e) orders, or which met certain hazard and exposure criteria.

This final rule significantly changes the proposed approach to provide a greater opportunity for public comment. EPA will issue SNURs under one of three procedures. The three mechanisms are: direct final rules, immediately effective interim final rules, and notice and comment rulemaking. EPA intends to use the direct final rulemaking process as its usual method for issuing new substance follow-up SNURs, but reserves the right to use immediately effective interim final or notice and comment rulemaking as appropriate.

Direct final rulemaking is the same as a procedure that is used by EPA for rulemaking under the Clean Air Act. In the **Federal Register** of June 23, 1982 (47 FR 27073), EPA discussed streamlining the State Implementation Plan (SIP) review process. In that notice, EPA announced that it would promulgate certain SIP revisions for which no public comment was expected using an "immediate final rulemaking." EPA has decided to adopt the same process for issuing SNURs under this rule because EPA does not generally anticipate public comment on these SNURs.

The process adopted for SNURs under this rule as "direct final rulemaking" works as follows: EPA will issue a document in the final rule section of the **Federal Register** which contains the final SNUR. The **Federal Register** document will state that the SNUR will be effective 60 days from the date of publication, unless, within 30 days from the date of publication, EPA receives written notice that someone intends to submit adverse or critical comments. If, within 30 days from the date of publication, EPA receives notice that someone intends to submit adverse or critical comments, EPA will withdraw the direct final rule by issuing a document in the final rule section of the **Federal Register**. EPA will simultaneously issue a proposed rule in the proposed rule section of the **Federal Register**. The proposed rule will establish a 30-day comment period, and will identify any objections to the rule of which EPA has been notified. EPA will then consider any comments received and decide either to issue a final rule promulgating the SNUR or withdraw the proposal.

EPA believes that this process provides an improved opportunity for public participation consistent with the objective of providing for prompt promulgation of SNURs to follow-up on new chemical substances. EPA will generally use this approach because it significantly reduces the time, relative to notice and comment rulemaking, during which a person may legally engage in a significant new use before the SNUR effective date. This option saves EPA resources because routinely only one **Federal Register** document is required to establish a SNUR.

Immediately effective interim final rules will work as follows: These SNURs will be issued as interim final rules and will be effective on the day of publication. A 30-day comment period begins on the day after publication. The rule ceases to be in effect 180 days from the date of publication unless during that time EPA issues a final rule addressing any comments received. This option provides the greatest possible reduction in the period during which a person may legally engage in an activity EPA intends to regulate as a significant new use because the rule is immediately effective and enforceable. EPA expects to use interim final rulemaking for SNURs when EPA has reason to believe that someone is likely to engage in the significant new use before the rule would go into effect under direct final or notice and comment rulemaking. EPA will explain its reasons when it uses this procedure for a specific SNUR.

EPA expects to follow notice and comment rulemaking procedures to issue SNURs in cases where it expects adverse or critical public comments on a SNUR. While this option maximizes the period during which a person may engage in the activity EPA intends to regulate under a SNUR, it also gives maximum public notice, and ensures a full period to address any significant issues. A full notice and comment cycle requires publication of two documents, and thus will cost more than the direct final method in most cases.

4. EPA had proposed that information submission requirements be imposed under TSCA section 8(d) for all substances, and under section 8(a) for some substances, subject to SNURs on an expedited basis. EPA has not adopted this aspect of the proposal. Such rules will be issued on a case-by-case basis as necessary, and consequently will not be issued under the expedited procedures of this final rule.

5. EPA's response to comments document (available in the public docket for this rule) supplements this preamble by addressing the public comments received on all aspects of this rule.

III. Provisions of the Final Rule

A. Amendments to Subparts A and B: Standard Language Describing Significant New Uses

Subpart A is amended to establish new definitions needed for the functioning of Subparts B, C, and D. The new Subpart B contains standard language which EPA will use in designating certain activities as significant new uses. Using standard language will reduce potential confusion due to minor language variations from SNUR to SNUR. When EPA wishes to designate an activity described by standardized language as a significant new use for a particular substance, it will list the substance in Subpart E and reference the appropriate standard new use language from Subpart B. Subpart B now contains the following sections:

§ 721.50 Applicability.
§ 721.63 Protection in the workplace.
§ 721.72 Hazard communication program.
§ 721.80 Industrial, commercial, and consumer activities.
§ 721.85 Disposal.
§ 721.90 Release to water.
§ 721.91 Computation of estimated surface water concentrations; instructions.

When appropriate standard language is not contained in Subpart B, EPA may amend Subpart B to add additional standardized language. This standard language will establish a significant new use for a particular new chemical substance only when it has been cited in a SNUR in Subpart E. EPA also intends to use standard provisions in section 5(e) consent orders; the standard SNUR language is designed to track the corresponding section 5(e) order provisions.

In codifying standard language for designation of significant new uses, it is not EPA's intent to discourage persons subject to SNURs from proposing more effective alternative approaches to limit exposure or environmental release. EPA encourages manufacturers, importers, and processors to seek approval of more effective alternative control measures under § 721.30.

1. *Section 721.63 Protection in the workplace.* This section designates new uses based on dermal and respiratory exposure and requires that employers demonstrate that chemical protective clothing is impervious to the substance. Changes from the proposal are designed to enable the Agency to more precisely cite exposures of concern and protective measures. The rule provides an exclusion from the workplace protection provision for mixtures containing low concentrations of the substance and establishes procedures persons must follow if they discover that their customers are engaging in activities inconsistent with the provisions of § 721.63(a).

i. *Dermal protection.* Section 721.63(a) will be cited whenever dermal exposure is a concern. This provision establishes a performance-based approach to dermal protection. The language allows employers to determine which employees are reasonably likely to be dermally exposed by evaluating the work area. Each employer has the responsibility to select, provide, and enforce the correct use of the appropriate personal protective equipment for dermal protection. Employer selection of control measures may take into account engineering controls and work practices instead of, or in addition to, personal protective equipment. Dermal protection applies only to persons who are reasonably likely to be dermally exposed. Reasonable and feasible engineering controls may often eliminate the need for personal protective equipment because the "reasonably likely to be exposed" finding will not be made. Under special circumstances EPA will cite the menu in § 721.63(a)(2) to specify the type of personal protective equipment that must be used for dermal protection in addition to the performance-based approach. A menu of physical forms at § 721.63(a)(6) allows the SNUR to establish controls appropriate to substances which have high vapor pressure and to which airborne exposures are likely as well as to substances which have low vapor pressure and to which airborne exposures are unlikely, consistent with a section 5(e) order on which the SNUR is based.

Section 721.63(b) exempts mixtures containing a concentration less than or equal to a concentration specified in Subpart E of this Part for a substance from dermal protection requirements, but excludes from exemption mixtures which might concentrate above the exemption limit. The concentration specified will ordinarily be one percent of the chemical substance (one tenth percent if the chemical substance is a carcinogen), which is consistent with the similar OSHA exemption, but other concentrations will be specified when appropriate. This exemption is not intended to cover a case where the substance is present in the mixture in concentrations greater than the level set in Subpart E of this Part, even though the airborne concentration of the mixture may be less than the level set in Subpart E of this Part.

EPA has added definitions for "work area" and "workplace" to Subpart A to clarify use of those terms in § 721.63. EPA developed the performance-based dermal protection provisions in response to comments favoring use of performance- based provisions whenever appropriate. EPA has retained standard language for describing specific types of personal protective equipment. EPA will cite this language when it determines that a particular type of personal protective equipment is essential for adequate worker protection.

ii. *Demonstration of imperviousness.* EPA requires that employers demonstrate that chemical protective clothing is impervious to the substance under the conditions and duration of exposure.

EPA is allowing two methods to demonstrate imperviousness: (a) Actual testing of the chemical protective clothing by the employer, and/or (b) evaluation of the chemical protective clothing manufacturer's specification data. EPA expects the demonstration of imperviousness will address the total environment to which the chemical protective clothing is exposed. EPA expects that factors affecting physical integrity such as abrasions, punctures, and tears will be considered. The employer must also consider penetration and permeation by the substance under the conditions and duration of exposure.

iii. *Respiratory protection.* Section 721.63 (a)(4) and (5) will be cited when inhalation exposure to the substance is a concern, and will specify the appropriate category of respirator for the substance from the lists contained in this section. The list of classes of respirators from which EPA will make selections has been expanded to provide a more complete range of options and a list of physical states has been added at § 721.63(a)(6) to allow EPA to specify protective measures against respiratory exposure from low-vapor pressure substances (e.g., acrylates) when they are used in a manner likely to cause exposure, while allowing the measures to be omitted when the substances are used in a manner not likely to cause the exposure.

EPA encourages employers to evaluate their work areas and to implement industrial hygiene programs that consider the use of engineering controls to reduce or eliminate inhalation exposure. If an employer wishes to use respiratory protection controls which differ from those specified in a SNUR, the employer may request EPA approval for their use under § 721.30.

EPA received comments suggesting that it adopt a performance-based approach to control respiratory exposure. EPA is considering development of performance-based provisions and will incorporate them into § 721.63 when developed. However, until performance-based provisions are available and the rule is amended, EPA will continue to specify respiratory protection equipment.

iv. *Low concentrations in mixtures.* As noted above, § 721.63(b) provides an exemption from use of controls on exposure when the substance is present in the workplace in a mixture with concentration of the substance less than or equal to a concentration specified in Subpart E of this Part for a substance from dermal protection requirements, but excludes from exemption mixtures which might concentrate above the exemption limit. The concentration specified will ordinarily be one percent of the chemical substance (one tenth percent if the chemical substance is a carcinogen), which is consistent with the similar OSHA exemption, but other concentrations will be specified when appropriate. The exemption would not apply if using or processing a mixture containing the substance at a concentration below the exemption level is likely to concentrate the substance above the exemption level. This exemption is not intended to cover a case where the substance is present in the mixture in concentrations greater than the level set in Subpart E of this Part, even though the airborne concentration of the mixture may be less than the level set in Subpart E of this Part. This exemption was not included in the proposed rule, but EPA has

included it in response to comments to enable the provisions of § 721.63 to be consistent with the provisions of § 721.72(e) and OSHA practice.

v. *Recipient activities inconsistent with a program for protection in the workplace.* Section 721.5(d), promulgated July 27, 1988 (53 FR 28354), sets forth procedures that persons subject to a SNUR (suppliers) must follow if they become aware that a customer is engaging in a significant new use, for example, the customer is not complying with workplace protection requirements. This section requires that the supplier stop distribution of the substance to that customer and notify EPA of the customer's failure to comply. EPA received comments that under some circumstances involving worker protection measures this requirement could be unnecessarily harsh. In response, EPA has added § 721.63(d), which allows the supplier to notify the customer in writing if its activities are inconsistent with a required worker protection program. If the supplier can then document that the customer has provided a written statement of assurance that appropriate measures to provide a worker protection program have been taken, the supplier is not required to stop supplying the customer. If a supplier later learns that the customer has failed to provide required worker protection, the supplier must stop distributing to that customer and follow the requirements of § 721.5(d).

2. *Section 721.72 Hazard communication program.*

i. *Introduction.* Section 721.72 establishes EPA's workplace hazard communication program. The section will be cited whenever EPA determines that it is necessary to inform workers of potential hazards and exposures in the workplace and how they must act to protect themselves under both routine and emergency conditions. EPA has received comments that a program will be easier to implement and more effective if it parallels the OSHA hazard communication standard to cover numerous existing chemicals which are present in the workplace. EPA agrees, and the provisions of § 721.72 parallel those of OSHA's standard where possible, but there are differences between the two. The most significant differences are: (a) The OSHA standard requires an employer to make a hazard determination, while in the EPA standard the hazard determination is made by EPA; (b) the OSHA standard allows the employer to develop language for labels and for the MSDS, while in § 721.72 EPA provides certain language to be included on the label and MSDS; (c) the OSHA standard has a trade secrets provision while § 721.72 does not; and (d) § 721.72 requires that environmental hazards be listed on the container label and the MSDS while the OSHA standard does not. The primary reason for the first two differences is that, in evaluating new substances, EPA is most often relying on a finding that a substance may present a risk, pending the development of additional data. OSHA's standard applies to substances for which more definitive data are available and which are known to present certain hazards. A separate trade secrets provision is not required, as section 14 of TSCA and EPA's rules issued to implement section 14 adequately address the issue. The fourth difference stems from EPA's broader mandate to protect the environment, as well as human health, from unreasonable risks.

ii. *Written hazard communication program.* Section 721.72(a) sets forth requirements for a written hazard communication program, which requires that each employer develops a written plan to ensure that employees who may be exposed to the substance will be made aware of the hazards involved, and specifies employee information and training, such as control measures to prevent employee exposure and release to the environment. The written program must be available to each employee, upon request. The proposed rule did not require a written hazard communication program. EPA included the written program in the final rule because EPA determined that a written program is necessary for a complete hazard communication program, and to parallel more closely the requirements of OSHA's standard, as suggested by commenters.

iii. *Labeling.* Section 721.72(b) sets forth labeling requirements for substances subject to § 721.72. It addresses both labeling of substances in the workplace and labeling for distribution in commerce. It requires information on both types of labels to alert employees to the possible health and environmental hazards of the substance and precautionary measures to prevent exposure and/or release to the environment. The label must refer the user to the MSDS for details. Container labels used outside the workplace must have the name and address of a responsible person who can be contacted for additional information on the substance, including appropriate emergency procedures.

iv. *Material safety data sheets.* Under § 721.72(c) an employer is required to obtain or develop an MSDS. The MSDS format is not specified by EPA; however, EPA does specify information that must be listed, if known, including: Physical and chemical characteristics, health and environmental hazards, signs and symptoms of exposure, medical conditions which may be aggravated by exposure, primary route(s) of exposure, and appropriate measures to control worker exposure and/or environmental release. The final rule does not make any substantive changes to the proposal.

An employer who distributes the substance must provide the MSDS at the time of the initial shipment and with the first shipment after each MSDS update. If the substance is not currently being produced, imported, processed, or used in the workplace, the employer must add new information to the MSDS before the substance is reintroduced into the workplace.

v. *Employee information and training.* The proposed employee information and training requirements have been changed to place more emphasis on training. The training and information must be provided at the time of initial employee assignment to a work area and whenever a substance subject to § 721.72 is introduced into the work area.

The employee information and training program must identify and address each substance subject to these provisions in the employee's work area. EPA intends that the employee who is reasonably likely to be exposed be made aware of and understand the health and environmental hazards of the substance and the control measures the employer is providing. This training requires an explanation of the MSDS required for each substance. All acute and chronic human health hazards known by the employer and identified in Subpart E must be listed, and the warning terms and phrases used to indicate the hazard must be explained. The personal protective equipment, engineering controls, and other measures used to control worker exposure and/or environmental release must be listed and explained. The training must also include methods and observations that may be used to detect the presence or release of each substance. Employees of contractors, and other workers not directly employed by the employer, must also receive the training and written materials, if the determination has been made that they are reasonably likely to be exposed to the substance.

Employees must also be given information to help them identify all operations in their work area where the

substance is present, and how they may be exposed. Employees must be informed about the specific requirements of the labeling program, the requirements for the MSDS, and all aspects of the hazard communication program that are relevant to their work assignments.

vi. *Low concentrations in mixtures.* Section 721.72(e) provides an exemption from the requirements of § 721.72 if a substance is present in the workplace only in a mixture containing a concentration less than or equal to a concentration specified in Subpart E of this Part for a substance, but excludes from exemption mixtures which might concentrate above the exemption limit. The concentration specified will ordinarily be one percent of the chemical substance (one tenth percent if the chemical substance is a carcinogen), which is consistent with the similar OSHA exemption, but other concentrations will be specified when appropriate.

This low concentration exemption was not included in the proposed rule. EPA decided to include this provision in response to comments which stated that without such an exemption the EPA program would be inconsistent with the OSHA standard.

vii. *Existing hazard communication program.* Section 721.72(f) clarifies the status of programs and procedures established under the OSHA standard and other rules. EPA intends that no unnecessary duplication of effort be required when complying with § 721.72. Commenters voiced their concerns about duplication of efforts because many already have a hazard communication program required under other rules. In all situations, if an employer is complying with another rule and those efforts meet or exceed the requirements of § 721.72, no additional action is necessary to comply with § 721.72.

viii. *Human and environmental hazard and precautionary statements.* Section 721.72(g) provides the standard language that EPA will specify for labels and MSDSs. EPA believes this standardization will provide consistency in content and organization to the writing of SNURs. EPA's requirements do not exclude the addition of other material to the labels and MSDSs, but they provide a minimum set of information which must be provided.

3. Section 721.80 *Industrial, commercial, and consumer activities.* Section 721.80 designates certain activities as significant new uses. Significant new uses described in this section include: Manufacture, processing, or use in non-enclosed processes; manufacture (except for export) of the substance associated with any use; use other than as an intermediate; use other than as a site-limited intermediate; use as an intermediate, where the concentration of the substance in products intended for distribution in commerce exceeds the percentage specified by EPA; non-industrial use; commercial use; use in a consumer product; annual manufacture and importation volume greater than that specified by EPA; and manufacture, processing, or use in physical forms specified by EPA.

Some commenters on the proposed rule stated that the uses described in § 721.80 are too broad and might require unnecessary notification. EPA has considered the comments, and has added additional uses where possible. For the most part, however, EPA has decided to promulgate the uses as proposed. EPA cannot predict and enumerate SNURs for every possible use variation that might lead to significant exposure or release. Often it is more practical to simply identify the category of use that is of concern. When EPA receives a significant new use notification, it will evaluate the specific use that is then proposed to determine whether it may present an unreasonable risk.

4. *Section 721.85 Disposal.* Section 721.85 designates specific ongoing or allowed disposal methods. Any other method is designated as a significant new use, requiring that manufacturers, importers, and processors submit a significant new use notice 90 days before employing such a disposal method.

Some commenters argued that the provisions of § 721.85 duplicate EPA rules issued under the Resource Conservation and Recovery Act and are, therefore, unnecessary. EPA intends to include disposal provisions in SNURs when it determines that disposal of the substance may not be adequately addressed by existing disposal rules. EPA can consider requests to limit or revoke SNURs under the provisions of § 721.85, if submitters believe they are in fact redundant.

5. *Section 721.90 Release to water.* Section 721.90 contains standard language for designating significant new uses involving release to water. Section 721.90(a) addresses manufacture streams, § 721.90(b) addresses processing streams, and § 721.90(c) addresses use streams. Section 721.90 (a)(2), (b)(2), and (c)(2) include a list of treatment technologies. EPA may specify one or more of these technologies for a substance if it determines that release without application of the specified treatment technology would constitute a significant new use. Section 721.90 (a)(4), (b)(4), and (c)(4) require notification only if the predicted environmental concentrations exceed a specified level.

In the proposed rule, reporting requirements for release to water were addressed in two sections. One covered process streams, the other, use streams. The definition of process stream had included both processing and manufacture. EPA determined that it will not always be appropriate to require reporting for both processing and manufacture, so it has modified the language of the rule to allow each to be specified separately as well as to specify them together. To do so, EPA has added a definition for manufacturing stream and sharpened the definition of processing stream so that it does not include manufacturing, and has established separate sections for manufacturing and for processing (§ 721.90 paragraphs (a)(2) and (b)(2)), allowing them to be specified separately. In cases where each should be a significant new use, both will be specified.

Section 721.91 provides a formula to be used in projecting environmental concentrations under § 721.90 (a)(4), (b)(4), and (c)(4). A commenter noted that the formula established in § 721.91 for calculating estimated surface water concentrations is difficult to use. EPA reviewed the formula but has been unable to devise a simpler calculation that would be suitable for general use. EPA will consider alternative mechanisms for calculation on a case-by-case basis, and may employ them if it determines that they are similar and will lead to a reliable projection of environmental concentration.

B. Subpart C: Recordkeeping and Other Requirements

Subpart C establishes recordkeeping requirements which apply to manufacturers, importers, and processors of SNUR substances. The specific records which are required depend upon the activities which have been designated as significant new uses. EPA will specify the appropriate recordkeeping requirements in Subpart E at the time it issues the SNUR for a particular substance. Such records must be maintained for 5 years from the date of their creation.

Several commenters voiced concerns that they will be required to keep separate records to document compliance with SNURs when records kept under other regulatory programs

should suffice to demonstrate compliance. In general, EPA has sought to frame recordkeeping requirements in flexible, performance- oriented terms. Rather than specify the particular types of records that must be kept, the rule lists the general types of information required to document compliance with SNUR requirements. Thus, manufacturers, importers, and processors will have discretion to determine which specific records must be retained. The records required to be maintained under this section often will be normal business records, and EPA intends that normal business records will usually suffice. In a few cases, the generation of additional records will be required. It is the responsibility of the manufacturer, importer, or processor to assess the adequacy of existing records, add to them if necessary, and maintain them in a form accessible to EPA for the required length of time.

EPA expects firms subject to SNUR requirements to exercise reasonable judgment in determining the steps necessary to document compliance with SNUR requirements. Records that are sufficient to document SNUR compliance in one case may not be sufficient in another.

Table 1 illustrates EPA's approach to recordkeeping by providing examples of the records that might document compliance with different SNUR requirements. These examples are intended merely to be illustrative. In many cases, the examples listed in the following Table 1 would be sufficient to document SNUR compliance; in other cases more or fewer records might be necessary.

TABLE 1—ADMINISTRATIVE EXAMPLES OF RECORDS COMPLYING WITH § 721.125

Significant New Use	Requirement	Examples
Disposal Methods.	Records demonstrating establishment and implementation of procedures that ensure compliance with any disposal limitations referenced in § 721.85.	Certificates of destruction from disposal facility. Bills of lading. Manifests. Waste treatment systems inventories.
Use in non-enclosed processes. Any manner or method of manufacture or processing in non-enclosed processes associated with any use. Use beyond the site of manufacture. Any manner or method of manufacture (excluding import) within the United States. Use other than as an intermediate. Use as an intermediate where the concentration of the intermediate substance in the product intended for distribution in commerce exceeds X percent. Non-industrial use. Commercial use. Use in a consumer product. Use other than as site-limited intermediate.	Records documenting compliance with any applicable industrial, commercial, and consumer use limitation referenced in § 721.80.	Batch slips. Process descriptions. Chemical inventory/plant inventory. Storage and production records.
Use in the form of a powder. Any manner or method of manufacture or processing in the form of a powder associated with any use (or other form). Use involving application methods that generate vapors, mists, or aerosols. Use involving application methods that generate dusts.	Records documenting compliance with any applicable industrial, commercial, and consumer use limitation referenced in § 721.80.	Process description.
Hazard Communication Employee Training.	Records documenting establishment and implementation of a program for employee information and training referenced in § 721.72.	Written hazard communication program. Attendance sheets from training sessions. Copies of written materials distributed at training sessions. Copies of labels. Copies of MSDSs.
Hazard Communication Labeling.	Records documenting the names and addresses of all persons to whom the substance is sold or transferred, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date. Copies of labels used.	Bills of sale. Copies of labels.
Manufacture, import, or processing without establishing a program whereby persons who may be dermally exposed to the substance are required to wear protective clothing, impervious gloves, and goggles.	Records documenting establishment and implementation of a program for the use of personal protective equipment referenced in § 721.63(a). Records documenting determinations under § 721.63(a)(3) that protective gloves are impervious to the substance.	Written hazard communication program. For gloves—Specifications supplied by the manufacturer of gloves; results of tests done on gloves. Attendance sheets from training sessions.
Manufacture, import, or processing without establishing a program whereby persons who may be exposed to the substance in the form of an aerosol or mist are required to wear respirators.	Records documenting establishment and implementation of a program for the use of personal protective equipment referenced in § 721.63(a).	Written hazard communication program. Process descriptions. Records of fit tests. Attendance sheets from training sessions.
Annual production volume greater than X.	Records documenting the manufacture and importation volume of the substance.	Production records. Import records.

TABLE 1—ADMINISTRATIVE EXAMPLES OF RECORDS COMPLYING WITH § 721.125—Continued

Significant New Use	Requirement	Examples
Water Release Limitations.	Records demonstrating establishment and implementation of procedures that ensure compliance with any water discharge limitations referenced in § 721.90.	Process description diagram (as described in § 721.91). Equation computation and paperwork supporting equation results.

C. Subpart D: Expedited Process for Issuing SNURs for New Chemical Substances; Limitation and Revocation of New Chemical Substance SNURs

Subpart D establishes at §§ 721.160, 721.170, and 721.185 expedited procedures for promulgation of, and for modifying or revoking, SNURs for new chemical substances.

1. *SNUR requirements for new chemical substances regulated under section 5(e) orders.* Section 721.160 establishes expedited procedures for issuing SNURs for new substances that are subject to TSCA section 5(e) orders. The SNUR issued for each substance will be based on and be consistent with the provisions included in the section 5(e) order governing use of the substance. EPA may also designate additional uses as significant new uses for such substances under the rulemaking procedures and criteria of § 721.170.

i. *Substances subject to section 5(e) orders issued before the effective date of this rule.* EPA requested comment in the 1987 proposal on whether § 722.160 (now § 721.160) should be applied to substances subject to section 5(e) orders negotiated prior to the effective date of this rule. All commenters addressing this issue requested that EPA modify the rule to do so. EPA has modified § 721.160 so that it can be applied to substances subject to section 5(e) orders issued prior to the effective date of this rule. If the notice of commencement of manufacture for the substance was received prior to the effective date of this rule, the direct final, interim final, or proposed SNUR will be issued within 1 year of the effective date of this rule. If the notice of commencement of manufacture is received after the effective date of this rule, the direct final, interim final, or proposed SNUR will be issued within 180 days of receipt of the notice. If EPA receives adverse or critical comments on a proposed SNUR, publication of the final rule may be delayed.

ii. *Non-issuance of SNURs for substances made subject to section 5(e) orders.* EPA will generally issue SNURs for substances made subject to section 5(e) orders. However, in cases where EPA believes that there is little likelihood that there will be manufacturers or processors other than the PMN submitter, or for other reasons believes that a SNUR for the substance is inappropriate, EPA may decide not to issue a SNUR for a substance subject to a section 5(e) order. In such cases EPA will issue a notice in the **Federal Register** explaining its reasons for not issuing a SNUR. EPA expects that such cases will be rare.

2. *SNUR requirements for new chemical substances not regulated under a section 5(e) order.* Section 721.170 establishes expedited procedures for issuing SNURs to regulate activities not covered in a section 5(e) order. Additionally, it establishes criteria for choosing which substances will be regulated ("concern criteria"), and limits the uses for which SNURs will be written, under the procedures of the section.

i. *Criteria other than concern criteria.* EPA will only designate an activity as a significant new use under § 721.170 if the activity was not described in the PMN for the substance, and the activity also satisfies a concern criterion established at § 721.170(b). Such a use may be made subject to a SNUR under this section whether or not a section 5(e) order is written for any other use of the substance described in the PMN. Procedures for issuing SNURs under § 721.170 are in § 721.170(c).

EPA decided that certain designations in § 721.80 are, by their nature, not appropriate for expedited SNURs issued under the procedure described in § 721.170. Expedited procedures will be used to issue SNURs including these designations only for SNURs based on section 5(e) orders. These designations include, for example, designation of uses other than those described in the PMN described in § 721.80(j), designation of cumulative manufacture or import in excess of specified quantities in the absence of test data (§ 721.80(r)), and the failure to use personal protective equipment (described in § 721.63).

Although these activities are not included under the expedited procedures of § 721.170, EPA may at any time include them in a SNUR adopted through separate rulemaking for a substance not subject to a section 5(e) order as long as it makes the findings specified in section 5(a)(2) of TSCA.

ii. *Concern criteria: information to be used in choice of substances.* Under § 721.170, SNURs may be issued for new substances if they meet the concern criteria established at § 721.170(b). These are generally similar criteria to those used by EPA in determining if a section 5(e) order should be developed. The criteria established at § 721.170(b) generally call for development of a SNUR if the exposures likely to result from uses not described in the PMN would have called for the development of a section 5(e) order if they had been described in a PMN.

Several commenters expressed the view that, under the language of the proposed rule, substances would be subject to SNURs on the basis of inadequate evidence. Appropriateness of EPA use of evidence was discussed at length in the public meetings held prior to publication of the proposed rule. A description of these discussions is in the public record for this rule. EPA believes that its criteria for concern are appropriate. In general, EPA regulates on the basis of the weight of the evidence available to it from all sources.

A commenter asked for restraint by EPA in use of structure activity relationship analysis (SAR) in assessing substances, and in framing SNUR restrictions for substances not subjected to a section 5(e) order. EPA makes its decisions based on the entire body of available evidence, and attempts to assign appropriate weight to each piece of evidence used. Often SAR is the best evidence available for new, little-tested substances. When better evidence is available, it will be given due consideration.

Two commenters requested that EPA convene open scientific meetings prior to issuance of this final rule to identify the best scientific basis for applying SAR. A commenter, noting that under the proposed rule notice and comment rulemaking would be curtailed, asked that EPA convene workshops and public meetings to receive comments on its use of SAR. In addition, the commenter asked that EPA annually reconvene the original Toxic Substances Dialogue

Group to assess how well the rule is working.

EPA is always interested in receiving comments and responses on its procedures and policies from regulated industry and the public. The change in this final rule from immediately effective final rules to procedures that will allow for public comment on each individual SNUR as necessary should provide adequate opportunity for comment on SAR use, and on the ongoing use of this rule.

Another commenter suggested that written SAR guidelines be released for public comment, and made a general request that scientific issues affecting PMN submitters receive the benefit of public comment.

EPA does not intend to maintain a written SAR guidance document. EPA use of SAR to assess the possible risk posed by a substance is based on professional judgment on a case-by-case basis. A general discussion of EPA's approach to SAR use was presented in the public discussions prior to the proposal, and is available in the public record maintained for this rulemaking.

EPA will hold meetings on its use of SAR and on other subjects as the need arises, but does not have plans for regular meetings at this time, nor does it foresee using the Dialogue Group as a formal ongoing advisory group.

3. *Procedures for issuing expedited SNURs.* The three procedures which may be used to issue SNURs under §§ 721.160 and 721.170 are: Direct final rulemaking, immediately effective interim final rulemaking, and notice and comment rulemaking. EPA will generally use direct final rulemaking to issue new substance SNURs, unless it determines that use of immediately effective interim final rulemaking or notice and comment rulemaking is more appropriate. EPA will use immediately effective interim final rulemaking in cases where it believes there may be particularly high potential hazard from uncontrolled use of the substance, or a particularly high likelihood that someone would engage in a significant new use between the time EPA announces its intention to issue a SNUR and the time the SNUR would take effect. When EPA determines that it is necessary to issue an immediately effective interim final SNUR, it will make the necessary findings and explain its reasons in the rule.

EPA will use notice and comment rulemaking to establish a SNUR when it believes there is a very high likelihood of public interest in commenting on the rule.

i. *Direct final rulemaking.* Under the direct final rulemaking process, EPA will issue a document in the final rule section of the **Federal Register** which contains the final SNUR. The **Federal Register** document will state that, unless written notice is received by EPA within 30 days of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from when the notice is published. If notice is received within 30 days that someone wishes to submit adverse or critical comments, EPA will withdraw the direct final rule by publishing a notice in the final rule section of the **Federal Register**, and EPA will propose a rule in the proposed rule section of the **Federal Register**. The proposed rule will establish a 30-day comment period. EPA then will consider any comments received and decide either to issue a final rule promulgating the SNUR or withdraw the proposal.

In implementing the provisions of Subpart D, EPA intends as much as possible to include more than one SNUR in a single **Federal Register** document to provide administrative efficiencies and save publication costs. With respect to direct final rulemaking procedures, when EPA publishes a number of SNURs in a single **Federal Register** document as direct final SNURs, the person notifying EPA of intent to submit adverse or critical comments will be asked to indicate to which SNUR the comments will apply. EPA would then publish a notice in the final rule section of the **Federal Register** withdrawing only that specific direct final SNUR and publish a separate proposal for that specific SNUR. However, EPA would not withdraw the direct final SNURs which are unaffected by the person's wish to submit adverse or critical comments.

ii. *Immediately effective interim final rules.* When using the interim final rulemaking procedure, EPA will issue a notice of interim final rulemaking. The rule will be effective on the day of publication; however, EPA will accept comments for 30 days following publication. The SNUR will cease to be in effect 180 days after publication unless in the intervening time EPA has issued a final rule addressing any comments received during the 30-day comment period.

iii. *Notice and comment rulemaking.* When EPA uses notice and comment rulemaking, EPA will first issue a proposed rule in the **Federal Register** stating that a SNUR will be developed for the substance, explaining the basis for the SNUR, listing the uses it proposes to designate as significant new uses, and soliciting public comment. After consideration of any comment on the proposed SNUR, EPA will issue a final rule adding the substance to Subpart E and identifying the significant new uses and recordkeeping requirements to which the substance is subject.

The proposed version of this Subpart D called for EPA to promulgate immediately effective final SNURs. Several commenters indicated that they did not believe that the proposed process would have given an adequate opportunity for public comment on the terms of SNURs before they went into effect. EPA has modified the rule to provide for opportunity for public comment in rulemaking for all SNURs. Additionally, EPA has substantially changed its internal review process to reduce the time it takes to propose and promulgate most SNURs under this subpart. This expedited internal review procedure will provide for the speedy protection of the public and equal treatment of PMN submitters and new users as contemplated in the April 29, 1987 proposal, but will allow public comments to be reviewed before the SNUR is promulgated as a final rule.

4. *Procedures to modify or revoke SNURs for new substances.* Section 721.185 establishes procedures to modify or revoke SNURs issued under this Subpart D, and informs the public of criteria EPA will consider in determining whether to do so. EPA may at any time modify the activities designated as significant new uses of a substance, or it may entirely revoke any specific significant new use notification requirement. EPA will consider modifying or revoking a SNUR issued under the expedited procedures of Subpart D, if other considerations do not justify retaining the SNUR unchanged, when it finds that one of the criteria at § 721.185(a) is met.

The procedures established under § 721.185 to petition EPA to modify or revoke SNURs are similar to those in TSCA section 21. Section 21 does not apply to SNURs.

Decisions to revoke or limit SNUR requirements may be made either at EPA's initiative or in response to a request by interested persons. Section 721.185(c) provides that EPA will respond by certified letter to a request for modification or revocation of a SNUR and, if EPA denies the request, will explain EPA's reasons for concluding that the SNUR requirements should remain in effect. Rules revoking or limiting SNURs under § 721.185 will be issued under notice and comment rulemaking procedures. Section 721.185 will help ensure that well-founded concerns about the validity of SNUR requirements are acted on expeditiously,

and that the public understands the procedure for modifying or limiting those requirements.

D. Removal of Proposed Information Requirements Under TSCA Sections 8(a) and (d)

In the proposed rule, EPA included procedures for automatically requiring reporting for certain new substances under TSCA section 8(a) at 40 CFR Part 704 and section 8(d) at 40 CFR Part 716. A commenter suggested that EPA carefully consider the conditions under which section 8(a) reporting on a substance that has been the subject of a SNUR is appropriate. EPA has considered the need to issue these information collection rules in an expedited manner, and has decided not to do so. When section 8(a) and (d) rules are appropriate for new substances, EPA will issue them on a case-by-case basis.

IV. Economic Analysis

EPA has evaluated the potential costs and benefits of establishing significant new use requirements for manufacture, import, and processing of new chemical substances under the procedures established in this rule. EPA's complete analysis is available in the public record for this rule (OPTS-50553B). The analysis is summarized in the preamble to the proposed rule. The costs and benefits of this final rule do not vary significantly from those described in the proposal.

V. *Rulemaking Record*

EPA has established a record for this rulemaking (docket control number OPTS-50553B). The record includes basic information considered by EPA in developing this rule. The record includes the following:

1. The proposed rules.
2. Comments received on the proposals leading to this rule.
3. Summaries of public meetings held to discuss the proposed rules.
4. The economic analysis of the rule.
5. Comment response document.
6. This final rule.

This record is available to the public in the TSCA Public Docket Office from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA Public Docket Office is located in Rm. NE-G004, 401 M St., SW., Washington, DC.

VI. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and, therefore, requires a Regulatory Impact Analysis. EPA has determined that this rule is not a "major rule" because it will not have an effect on the economy of $100 million or more, and it will not have a significant effect on competition, costs, or prices. EPA has determined this rule to be "significant," because it will represent a significant change in the New Chemical Follow-up Program under TSCA.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA has determined that this rule will not have a significant impact on a substantial number of small businesses. EPA cannot determine whether parties affected by this rule are likely to be small businesses. However, EPA believes that the number of small businesses affected by this rule will not be substantial even if all the companies affected by this rule are small companies. EPA does not expect to regulate a large number of substances annually under this rule.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by OMB under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2070-0012.

Public reporting burden for this collection of information is estimated to average 12.2 hours per response for Subpart B, and to average 25.3 hours per response for Subpart C, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 721

Chemicals, Confidential business information, Environmental protection, Hazardous substances, Health and safety, Imports, Recordkeeping and reporting requirements, Significant new uses.

Dated: July 14, 1989.

F. Henry Habicht,

Acting Administrator.

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

Therefore, 40 CFR Chapter I is amended as follows:

1. By revising the authority citation for Part 721 to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. In § 721.3 by alphabetically adding the following definitions:

§ 721.3 Definitions.

* * * * *

"Acutely toxic effects" A chemical substance produces acutely toxic effects if it kills within a short time period (usually 14 days):

(1) At least 50 percent of the exposed mammalian test animals following oral administration of a single dose of the test substance at 25 milligrams or less per kilogram of body weight (LD_{50}).

(2) At least 50 percent of the exposed mammalian test animals following dermal administration of a single dose of the test substance at 50 milligrams or less per kilogram of body weight (LD_{50}).

(3) At least 50 percent of the exposed mammalian test animals following administration of the test substance for 8 hours or less by continuous inhalation at a steady concentration in air at 0.5 milligrams or less per liter of air (LC_{50}).

* * * *

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

* * * * *

"Director of the Office of Toxic Substances" means the Director of the EPA Office of Toxic Substances or any EPA employee delegated by the Office Director to carry out the Office Director's functions under this part.

"Employer" means any manufacturer, importer, processor, or user of chemical substances or mixtures.

"Environmentally transformed" A chemical substance is "environmentally transformed" when its chemical structure changes as a result of the action of environmental processes on it.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use" A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious" Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

* * * * *

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

* * * * *

"MSDS" means material safety data sheet, the written listing of data for the chemical substance as required under § 721.72(c).

* * * * *

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

* * * * *

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

* * * * *

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

* * * * *

"Serious acute effects" means human injury or human disease processes that have a short latency period for development, result from short-term exposure to a chemical substance, or are a combination of these factors and which are likely to result in death or severe or prolonged incapacitation.

"Serious chronic effects" means human injury or human disease processes that have a long latency period for development, result from long-term exposure to a chemical substance, or are a combination of these factors and which are likely to result in death or severe or prolonged incapacitation.

"Short-term test indicative of carcinogenic potential" means either any limited bioassay that measures tumor or preneoplastic induction, or any test indicative of interaction of a chemical substance with DNA (i.e., positive response in assays for gene mutation, chromosomal aberrations, DNA damage and repair, or cellular transformation).

"Short-term test indicative of the potential to cause a developmentally toxic effect" means either any *in vivo* preliminary development toxicity screen conducted in a mammalian species, or any *in vitro* developmental toxicity screen, including any test system other than the intact pregnant mammal, that has been extensively evaluated and judged reliable for its ability to predict the potential to cause developmentally toxic effects in intact systems across a broad range of chemicals or within a class of chemicals that includes the substance of concern.

"Significant adverse environmental effects" means injury to the environment by a chemical substance which reduces or adversely affects the productivity, utility, value, or function of biological, commercial, or agricultural resources, or which may adversely affect a threatened or endangered species. A substance will be considered to have the potential for significant adverse environmental effects if it has one of the following:

(1) An acute aquatic EC_{50} of 1 mg/L or less.

(2) An acute aquatic EC_{50} of 20 mg/L or less where the ratio of aquatic vertebrate 24-hour to 48-hour EC_{50} is greater than or equal to 2.0.

(3) A Maximum Acceptable Toxicant Concentration (MATC) of less than or equal to 100 parts per billion (100 ppb).

(4) An acute aquatic EC_{50} of 20 mg/L or less coupled with either a measured bioconcentration factor (BCF) equal to or greater than 1,000x or in the absence of bioconcentration data a log P value equal to or greater than 4.3.

* * * * *

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

* * * * *

"Work area" means a room or defined space in a workplace where a chemical substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

3. By adding a new Subpart B to Part 721 to read as follows:

Subpart B—Certain Significant New Uses

Sec.

721.50 Applicability.
721.63 Protection in the workplace.
721.72 Hazard communication program.
721.80 Industrial, commercial, and consumer activities.
721.85 Disposal.

Sec.
721.90 Release to water.
721.91 Computation of estimated surface water concentrations; instructions.

Subpart B—Certain Significant New Uses

§ 721.50 Applicability.

This Subpart B identifies certain significant new uses of chemical substances identified in Subpart E of this part. The provisions of this Subpart B apply only when referenced as applying to a chemical substance identified in Subpart E of this part.

§ 721.63 Protection in the workplace.

(a) Whenever a substance is identified in Subpart E of this part as being subject to this section, a significant new use of the substance is any manner or method of manufacturing, importing, or processing associated with any use of the substance without establishing a program whereby:

(1) Each person who is reasonably likely to be dermally exposed in the work area to the chemical substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in the form listed in paragraph (a)(6) of this section, and cited in Subpart E of this part for the chemical substance, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with 29 CFR 1910.132 and 1910.133.

(2) In addition to any other personal protective equipment selected in paragraph (a)(1) of this section, the following items are required:

(i) Gloves.

(ii) Full body chemical protective clothing.

(iii) Chemical goggles or equivalent eye protection.

(iv) Clothing which covers any other exposed areas of the arms, legs, and torso. Clothing provided under this paragraph need not be tested or evaluated under the requirements of paragraph (a)(3) of this section.

(3) The employer is able to demonstrate that each item of chemical protective clothing, including gloves, selected provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(ii) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the chemical substance alone and in likely combination with other chemical substances in the work area.

(4) Each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in Subpart E of this part for the chemical substance, is provided with, and is required to wear, at a minimum, a NIOSH- approved respirator from one of the categories listed in paragraph (a)(5) of this section, and the respirator is used in accordance with 29 CFR 1910.134 and 30 CFR Part 11.

(5) The following NIOSH approved respirators meet the minimum requirements for paragraph (a)(4) of this section:

(i) Category 19C Type C supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a full facepiece.

(ii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece.

(iii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet or tight-fitting facepiece.

(iv) Category 21C air-purifying respirator equipped with a full facepiece and high efficiency particulate filters.

(v) Category 21C powered air-purifying respirator equipped with a tight-fitting facepiece and high efficiency particulate filters.

(vi) Category 21C powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate filters.

(vii) Category 21C air-purifying respirator equipped with a high efficiency particulate filter including disposable respirators.

(viii) Category 23C air-purifying respirator equipped with a full facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(ix) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(x) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xi) Category 23C air-purifying respirator equipped with combination cartridges approved for paints, lacquers, and enamels, including disposable respirators. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xii) Category 23C air-purifying respirator equipped with a full facepiece and organic gas/vapor cartridges.

(xiii) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and organic gas/vapor cartridges.

(xiv) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and organic gas/vapor cartridges.

(xv) Category 23C air-purifying respirator equipped with organic gas/vapor cartridges, including disposable respirators.

(6) When cited in Subpart E of this part for a substance, the following airborne form(s) of the substance apply to paragraphs (a)(1) and (4) of this section:

(i) Dust.

(ii) Mist.

(iii) Fume.

(iv) Smoke.

(v) Vapor.

(vi) Gas.

(b) If a substance identified in Subpart E of this part is present in the work area only as a mixture, an employer is exempt from the provisions of this section if the concentration of the substance in the mixture does not exceed a concentration set in Subpart E of this part. The exemption does not apply if the employer has reason to believe that during intended use or processing in the work area, the substance in the mixture may be concentrated above the level set in Subpart E of this part.

(c)(1) If at any time after commencing distribution in commerce of a chemical substance that is identified in Subpart E of this part as subject to this section, the

person has knowledge that a recipient of the substance is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section, the person is considered to have knowledge that the recipient is engaging in a significant new use and is required to follow the procedures in § 721.5(d) unless the person is able to document the following:

(i) That the person has notified the recipient in writing within 15 working days of the time the person first has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section, and that the person has knowledge of the failure of implementation.

(ii) That within 15 working days of notifying the recipient that the recipient is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section the person has received from the recipient, in writing, a statement of assurance that the recipient has established the program required under paragraph (a) of this section, and will take appropriate measures to avoid activities that are inconsistent with implementation of the program required under paragraph (a) of this section.

(2) If, after receiving a statement of assurance from a recipient under paragraph (c)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of the program specified in paragraph (a) of this section, that person is considered to have knowledge that the person is engaging in a significant new use and is required to follow the procedures in § 721.5(d).

§ 721.72 Hazard communication program.

Whenever a substance is identified in Subpart E of this part as being subject to this section, a significant new use of that substance is any manner or method of manufacture, import, or processing associated with any use of that substance without establishing a hazard communication program as described in this section.

(a) *Written hazard communication program.* Each employer shall develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this paragraph. The written program shall include the following:

(1) A list of each substance identified in Subpart E of this part as subject to this section known to be present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate MSDS for each substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas.

(2) The methods the employer will use to inform employees of the hazards of non-routine tasks involving the substance, for example, the cleaning of reactor vessels, and the hazards associated with the substance contained in unlabeled pipes in their work area.

(3) The methods the employer will use to inform contractors of the presence of the substance in the employer's workplace and of the provisions of this part applicable to the substance if employees of the contractor work in the employer's workplace and are reasonably likely to be exposed to the substance while in the employer's workplace.

(b) *Labeling.* (1) Each employer shall ensure that each container of the substance in the workplace is labeled in accordance with this paragraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of health hazard(s) and precautionary measure(s) for the substance, if any, identified in Subpart E of this part or by the employer.

(B) The identity by which the substance may be commonly recognized.

(C) A statement of environmental hazard(s) and precautionary measure(s) for the substance, if any, identified in Subpart E of this part or by the employer.

(D) A statement of exposure and precautionary measure(s), if any, identified in Subpart E of this part or by the employer.

(ii) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by paragraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The employer need not label portable containers into which the substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The employer shall not remove or deface an existing label on incoming containers of the substance unless the container is immediately relabeled with the information specified in paragraph (b)(1)(i) of this section.

(2) Each employer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this paragraph.

(i) The label shall, at a minimum, contain the following information:

(A) The information required under paragraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing a substance identified in Subpart E of this part as subject to this section in combination with another substance identified in Subpart E of this part and/or a substance defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the employer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the employer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under Subpart E of this part, the employer

must seek a determination of equivalency for such alternative control measures pursuant to § 721.30 before prescribing them under this paragraph.

(c) *Material safety data sheets.* (1) Each employer must obtain or develop a MSDS for the substance.

(2) Each MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the substance under this section, and, if not claimed confidential, the chemical and common name of the substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the employer (such as vapor pressure, flash point).

(iii) The physical hazards of the substance known to the employer, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in Subpart E of this part for the substance.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the substance known to the employer.

(vi) The primary routes of exposure to the substance.

(vii) Precautionary measures to control worker exposure and/or environmental release identified in Subpart E of this part for the substance, or alternative control measures which EPA has determined under § 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the substance which are known to the employer, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the employer, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the employer.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the individual preparing or distributing the MSDS, or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the employer must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the employer may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the employer becomes aware of any significant new information regarding the hazards of the substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the employer becomes aware of the new information. If the substance is not currently being manufactured, imported, processed, or used in the employer's workplace, the employer must add the new information to the MSDS before the substance is reintroduced into the workplace.

(6) The employer must ensure that persons receiving the substance from the employer are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The employer may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The employer must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for each substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) *Employee information and training.* Each employer must ensure that employees are provided with information and training on the substance identified in Subpart E of this part. This information and training must be provided at the time of each employee's initial assignment to a work area containing the substance and whenever the substance subject to this section is introduced into the employee's work area for the first time.

(1) Information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances identified in Subpart E of this part as subject to this section, and MSDSs required by paragraph (c) of this section.

(2) Training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the substance in or from an employee's work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the substance as specified in Subpart E of this part.

(iii) The measures employees can take to protect themselves and the environment from the substance, including specific procedures the employer has implemented to protect employees and the environment from exposure to the substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under Subpart E of the part, or alternative control measures which EPA has determined under § 721.30 provide substantially the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the employer under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) *Low concentrations in mixtures.* If a substance identified in Subpart E of this part is present in the work area only as a mixture, an employer is exempt from the provisions of this section if the concentration of the substance in the mixture does not exceed a concentration set in Subpart E of this part. The exemption does not apply if the employer has reason to believe that during intended use or processing in the work area, the substance in the mixture may be concentrated above the level set in Subpart E of this part.

(f) *Existing hazard communication program.* The employer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) *Human health, environmental hazard, exposure, and precautionary statements.* Whenever referenced in Subpart E of this part for a substance, the following human health and environmental hazard, exposure, and precautionary statements shall appear on each label as specified in paragraph (b) of this section and the MSDS as specified in paragraph (c) of this section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

(1) Human health hazard statements: This substance may cause:

(i) Skin irritation.

(ii) Respiratory complications.

(iii) Central nervous system effects.

(iv) Internal organ effects.

(v) Birth defects.

(vi) Reproductive effects.

(vii) Cancer.

(viii) Immune system effects.

(ix) Developmental effects.

(2) Human health hazard precautionary statements: When using this substance:

(i) Avoid skin contact.

(ii) Avoid breathing substance.

(iii) Avoid ingestion.

(iv) Use respiratory protection.

(v) Use skin protection.

(3) Environmental hazard statements: This substance may be:

(i) Toxic to fish.

(ii) Toxic to aquatic organisms.

(4) Environmental hazard precautionary statements: Notice to users:

(i) Disposal restrictions apply.

(ii) Spill clean-up restrictions apply.

(iii) Do not release to water.

(5) Each human health or environmental hazard precautionary statement identified in Subpart E of this part for the label on the substance container must be followed by the statement, "See MSDS for details."

§ 721.80 Industrial, commercial, and consumer activities.

Whenever a substance is identified in Subpart E of this part as being subject to this section, a significant new use of the substance is:

(a) Use in non-enclosed processes.

(b) Any manner or method of manufacture in non-enclosed processes associated with any use.

(c) Any manner or method of processing in non-enclosed processes associated with any use.

(d) Use beyond the site of manufacture or import.

(e) Processing beyond the site of manufacture or import.

(f) Any manner or method of manufacture (excluding import) of the substance associated with any use.

(g) Use other than as an intermediate.

(h) Use other than as a site-limited intermediate.

(i) Use as an intermediate where the concentration of the intermediate substance in the product intended for distribution in commerce exceeds the concentration specified in Subpart E of this part for the substance.

(j) Use other than as described in the premanufacture notice referenced in Subpart E of this part for the substance.

(k) Use other than allowed by the section 5(e) consent order referenced in Subpart E of this part for the substance.

(l) Non-industrial use.

(m) Commercial use.

(n) Non-commercial use.

(o) Use in a consumer product.

(p) Aggregate manufacture and importation volume for any use greater than that specified in Subpart E of this part for the substance.

(q) Aggregate manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order referenced in Subpart E of this part for the substance.

(r) Aggregate manufacture and importation volume for any use greater than that specified in Subpart E of this part for the substance unless the manufacturer or importer has submitted the results of the health or environmental effects studies identified in Subpart E of this part for the substance and those studies comply with the procedures and criteria for developing and evaluating data identified in Subpart E of this part for the substance.

(s) Annual manufacture and importation volume for any use greater than that specified in Subpart E of this part for the substance.

(t) Annual manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order referenced in Subpart E of this part for the substance.

(u) Annual manufacture and importation volume for any use greater than that specified in Subpart E of this part for the substance unless the manufacturer or importer has submitted the results of the health or environmental effects studies identified in Subpart E of this part for the substance and those studies comply with the procedures and criteria for developing and evaluating data identified in Subpart E of this part for the substance.

(v) Use in the form of:

(1) A powder.

(2) A solid.

(3) A liquid.

(4) A gas.

(w) Any manner or method of manufacture of the substance in the following form associated with any use:

(1) A powder.

(2) A solid.

(3) A liquid.

(4) A gas.

(x) Any manner or method of processing of the substance in the following form associated with any use:

(1) A powder.

(2) A solid.

(3) A liquid.

(4) A gas.

(y) Use involving an application method that generates:

(1) A vapor, mist, or aerosol.

(2) A dust.

§ 721.85 Disposal.

Whenever a substance is identified in Subpart E of this part as being subject to this section, a significant new use of the substance is any method of:

(a) Disposal of the process stream associated with any use of the substance or with any manner or method of manufacturing associated with any use of the substance other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(b) Disposal of the process stream associated with any use or with any manner or method of processing associated with any use other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(c) Disposal of the use stream associated with any use, other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(d) Disposal of the substance associated with any use of the substance, or with any manner or method of manufacture or processing in association with any use. This provision does not supercede any applicable Federal, State, or local laws and regulations.

§ 721.90 Release to water.

Whenever a substance is identified in Subpart E of this part as being subject to this section, a significant new use of the substance is:

(a) Any predictable or purposeful release of a manufacturing stream associated with any use of the substance, from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in Subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling.

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR Part 133.

(4) Into the waters of the United States if the quotient from the following formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds the level specified in Subpart E of this part when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, monitoring or alternative calculations may be used to predict the surface water concentration which will result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

(b) Any predictable or purposeful release of a process stream containing the substance associated with any use of the substance from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in Subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling.

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR Part 133.

(4) Into the waters of the United States if the quotient from the following formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds the level specified in Subpart E of this part when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, monitoring or alternative calculations may be used to predict the surface water concentration which will result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

(c) Any predictable or purposeful release of a use stream containing the substance associated with any use of the substance from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in Subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling.

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR Part 133.

(4) Into the waters of the United States if the quotient from:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds the level specified in Subpart E of this part, when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, however, monitoring or alternative calculations may be used to predict the surface water concentration expected to result from intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

§ 721.91 Computation of estimated surface water concentrations: instructions.

These instructions describe the use of the equation specified in § 721.90(a)(4) and (b)(4) to compute estimated surface water concentrations which will result from release of a substance identified in Subpart E of this part. The equation shall be computed for each site using the stream flow rate appropriate for the site according to paragraph (b) of this section, and the highest number of kilograms calculated to be released for that site on a given day according to paragraph (a) of this section. Two variables shall be considered in computing the equation, the number of kilograms released, and receiving stream flow.

(a) *Number of kilograms released.* (1) To calculate the number of kilograms of substance to be released from manufacturing, processing, or use operations, as specified in the numerator of the equation, develop a process description diagram which describes each manufacturing, processing, or use operation involving the substance. The process description must include the

major unit operation steps and chemical conversions. A unit operation is a functional step in a manufacturing, processing, or use operation where substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics. Include steps in which the substance is formulated into mixtures, suspensions, solutions, etc.

(2) Indicate on each diagram the entry point of all feedstocks (e.g., reactants, solvents, and catalysts) used in the operation. Identify each feedstock and specify its approximate weight regardless of whether the process is continuous or batch.

(3) Identify all release points from which the substance or wastes containing the substance will be released into air, land, or water. Indicate these release points on the diagram. Do not include accidental releases or fugitive emissions.

(4) For releases identified in the diagram that are destined for water, estimate the amount of substance that will be released before the substance enters control technology. The kilograms of substance released may be estimated based on:

(i) The mass balance of the operation, i.e., totaling inputs and outputs, including wastes for each part of the process such that outputs equal inputs. The amount released to water may be the difference between the amount of the substance in the starting material (or formed in a reaction) minus the amount of waste material removed from each part of the process and not released to water and the amount of the substance in the final product.

(ii) Physical properties such as water solubility where a known volume of water being discharged is assumed to contain the substance at concentrations equal to its solubility in water. This approach is particularly useful where the waste stream results from separation of organic/water phases or filtration of the substance from an aqueous stream to be discharged.

(iii) Measurements of flow rates of the process/use stream and known concentrations of the substance in the stream.

(5) After releases of a substance to water are estimated for each operation on a site, total the releases of the substance to water from all operations at that site. The value (number of kilograms) specified in the numerator of the equation should reflect total kilograms of substance released to water per day from all operations at a single site.

(6) Use the highest expected daily release of the substance for each site.

(b) *Receiving stream flow.* (1) The receiving stream flow shall be expressed in million liters per day (MLD). The flow rate data to be used must be for the point of release on the water body that first receives release of the substance whether by direct discharge from a site, or by indirect discharge through a Publicly-Owned Treatment Works (POTW) for each site. The flow rate reported shall be the lowest 7-day average stream flow with a recurrence interval of 10 years (7-Q- 10). If the 7-Q-10 flow rate is not available for the actual point of release, the stream flow rate should be used from the U.S. Geological Survey (USGS) gauging station that is nearest the point of release that is expected to have a flow rate less than or equal to the receiving stream flow at the point of release.

(2) Receiving stream flow data may be available from the National Pollutant Discharge Elimination System (NPDES) permit for the site or the POTW releasing the substance to surface water, from the NPDES permit-writing authority for the site or the POTW, or from USGS publications, such as the water-data report series.

(3) If receiving stream flow data are not available for a stream, either the value of 10 MLD or the daily flow of wastewater from the site or the POTW releasing the substance must be used as an assumed minimum stream flow. Similarly, if stream flow data are not available because the location of the point of release of the substance to surface water is a lake, estuary, bay, or ocean, then the flow rate to be used must be the daily flow of wastewater from the site or the POTW releasing the substance to surface water. Wastewater flow data may be available from the NPDES permit or NPDES authority for the site or the POTW releasing the substance to water.

4. By adding a new Subpart C to Part 721 to read as follows:

Subpart C—Recordkeeping Requirements

Sec.
721.100 Applicability.
721.125 Recordkeeping requirements.

Subpart C—Recordkeeping Requirements

§ 721.100 Applicability.

This Subpart C identifies certain additional recordkeeping requirements applicable to manufacturers, importers, and processors of substances identified in Subpart E of this part for each specific substance. The provisions of this Subpart C apply only when referenced in Subpart E of this part for a substance and significant new use identified in that Subpart E. If the provisions in this Subpart C conflict with general provisions of Subpart A of this part, the provisions of this Subpart C shall apply.

§ 721.125 Recordkeeping requirements.

At the time EPA adds a substance to Subpart E of this part, EPA will specify appropriate recordkeeping requirements which correspond to the significant new use designations for the substance selected from Subpart B of this part. Each manufacturer, importer, and processor of the substance shall maintain the records for 5 years from the date of their creation. In addition to the records specified in § 721.40, the records whose maintenance this section requires may include the following:

(a) Records documenting the manufacture and importation volume of the substance and the corresponding dates of manufacture and import.

(b) Records documenting volumes of the substance purchased in the United States by processors of the substance, names and addresses of suppliers, and corresponding dates of purchase.

(c) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture, importation, or processing to whom the manufacturer, importer, or processor directly sells or transfers the substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date.

(d) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required under § 721.63.

(e) Records documenting the determinations required by § 721.63(a)(3) that chemical protective clothing is impervious to the substance.

(f) Records documenting establishment and implementation of the hazard communication program required under § 721.72.

(g) Copies of labels required under § 721.72(b).

(h) Copies of material safety data sheets required under § 721.72(c).

(i) Records documenting compliance with any applicable industrial, commercial, and consumer use limitations under § 721.80.

(j) Records documenting compliance with any applicable disposal requirements under § 721.85, including the method of disposal, location of disposal sites, dates of disposal, and volume of the substance disposed. Where the estimated disposal volume is not known to or reasonably

ascertainable by the manufacturer, importer, or processor, that person must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

(k) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitations under § 721.90.

5. By adding a new Subpart D to Part 721 to read as follows:

Subpart D—Expedited Process for Issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules

Sec.

721.160 Notification requirements for new chemical substances subject to section 5(e) orders.
721.170 Notification requirements for selected new chemical substances that have completed premanufacture review.
721.185 Limitation or revocation of certain notification requirements.

Subpart D—Expedited Process for Issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules

§ 721.160 Notification requirements for new chemical substances subject to section 5(e) orders.

(a) *Selection of substances.* (1) In accordance with the expedited process specified in this section, EPA will issue significant new use notification requirements and other specific requirements for each new chemical substance that is the subject of a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture and import of the substance, unless EPA determines that significant new use notification requirements are not needed for the substance.

(2) If EPA determines that significant new use notification requirements are not needed for a substance that is subject to a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture or import of the substance, EPA will issue a notice in the **Federal Register** explaining why the significant new use requirements are not needed.

(b) *Designation of requirements.* (1) The significant new use notification and other specific requirements will be based on and be consistent with the provisions included in the final order issued for the substance under section 5(e) of the Act. EPA may also designate additional activities as significant new uses which will be subject to notification. Designation of additional activities as significant new uses will be done in accordance with the criteria and procedures under § 721.170, or through a separate rulemaking proceeding.

(2) Significant new use requirements and other specific requirements designated under this section will be listed in Subpart E of this part. For each substance, Subpart E will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses.

(iii) Other specific requirements applicable to the substance, including recordkeeping requirements or any other requirements included in the final section 5(e) order.

(c) *Procedures for issuing significant new use rules.* (1) EPA will issue significant new use rules under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(2) **Federal Register** documents issued to propose or establish significant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by EPA.

(ii) The premanufacture notice number.

(iii) The CAS number, where available and not claimed confidential.

(iv) A summary of EPA's findings under section 5(e)(1)(A) of the Act for the final order issued under section 5(e).

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of Subpart A of this part applicable to the specific substance and significant new uses.

(vii) If the **Federal Register** document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(3) *Direct final rulemaking.* (i) When EPA uses the direct final rulemaking procedure to issue a significant new use rule, it will issue a final rule in the **Federal Register** following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(ii) The **Federal Register** document will state that, unless written notice is received by EPA within 30 days of publication that someone wishes to submit adverse or critical comments, the rule will be effective 60 days from the date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the **Federal Register**, and a proposal will be published in the proposed rule section of the **Federal Register**. The proposal will establish a 30-day comment period.

(iii) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to Subpart E of this part and designating the significant new uses subject to notification.

(4) *Notice and comment rulemaking.* (i) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposal in the **Federal Register** following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(ii) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to Subpart E of this part and designating the significant new uses subject to notification.

(5) *Interim final rulemaking.* (i) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the **Federal Register** following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(A) The significant new use rule will take effect on the date of publication.

(B) Persons will be given 30 days from the date of publication to submit comments.

(ii) Interim final rules issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the **Federal Register** responding to any written comments received during the 30-day comment period specified in paragraph (c)(5)(i)(B) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(d) *Schedule for issuing significant new use rules.* (1) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 180 days of receipt of a valid notice of commencement under § 720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 1 year of October 10, 1989, for any substance for which the valid notice of commencement under § 720.102 of this chapter was received before October 10, 1989.

(3) If EPA receives adverse or critical significant comments following publication of a proposed or interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

§ 721.170 Notification requirements for selected new chemical substances that have completed premanufacture review.

(a) *Selection of substances.* In accordance with the expedited process specified in this section, EPA may issue significant new use notification and recordkeeping requirements for any new chemical substance for which a premanufacture notice has been submitted under Part 720 of this chapter if EPA determines that activities other than those described in the premanufacture notice may result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects.

(b) *Concern criteria.* EPA may determine that concern exists about a substance's health or environmental effects if EPA makes any one of the following findings:

(1)(i) The substance may cause carcinogenic effects because the substance:

(A) Has been shown by valid test data to cause carcinogenic effects in humans or in at least one species of laboratory animal.

(B) Has been shown to be a possible carcinogen based on the weight of the evidence in short-term tests indicative of the potential to cause carcinogenic effects.

(C) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by test data to cause carcinogenic effects in humans or in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(D) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause carcinogenic effects under the criteria in paragraphs (b) (1)(i)(A), (B), or (C) of this section.

(ii) No substance may be regulated based on a finding under paragraph (b)(1) of this section unless EPA has also made the finding under § 721.170(c)(2)(ii).

(2) The substance has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal or is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(3) The substance may cause serious chronic effects, serious acute effects, or developmentally toxic effects under reasonably anticipated conditions of exposure because the substance:

(i) Has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another chemical substance that has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause serious chronic effects, serious acute effects, or developmentally toxic effects under the criteria in paragraph (b) (3)(i) and (ii) of this section.

(iv) Has been shown to potentially cause developmentally toxic effects based on the weight of the evidence in short-term tests indicative of the potential to cause developmentally toxic effects.

(4) The substance may cause significant adverse environmental effects under reasonably anticipated conditions of release because the substance:

(i) Has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) Has been determined, based on calculations using the substance's physical and chemical properties, to be potentially able to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(iv) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be environmentally transformed to a substance which may have the potential to cause significant adverse environmental effects under the criteria in paragraph (b) (4)(i), (ii), and (iii) of this section.

(5) Concern exists about the health or environmental effects of one or more impurities or byproducts of the

substance because the impurity or byproduct meets one or more of the criteria in paragraph (b) (1) through (4) of this section and either:

(i) The impurity or byproduct is a new chemical substance and may be present in concentrations that could cause adverse health or environmental effects under reasonably anticipated conditions of exposure or release.

(ii) Reasonably anticipated manufacture, processing, or use activities involving the substance for which a premanufacture notice has been submitted may result in significantly increased human exposure to or environmental release of the impurity or byproduct compared to exposure or release levels resulting from existing activities involving the impurity or byproduct.

(c) *Designation of requirements.* (1) When EPA decides to establish significant new use reporting requirements under this section, it may designate as a significant new use one or more of the industrial, commercial, or consumer activities specified under § 721.80 (a) through (i), (l) through (o), and (v) through (y); environmental release activities specified under § 721.85 or § 721.90; or subcategories of these activities. In addition, EPA may designate specific requirements described under Subpart C of this part that are applicable to the substance.

(2) EPA may designate as a significant new use only those activities that (i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified under paragraph (b) of this section.

(d) *Procedures for issuing significant new use rules.* (1) Significant new use requirements designated under this section will be listed in Subpart E of this part. For each substance, Subpart E of this part will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses, which may include one or more of the activities described in paragraph (c) of this section.

(iii) Other specific requirements applicable to the substance.

(2) When EPA determines that a substance is a candidate for a significant new use rule under this section, it will notify the person that submitted the premanufacture notice for the substance no later than 7 calendar days before the expiration of the notice review period under § 720.75 of this chapter. In providing this notice, EPA will describe the health or environmental concerns identified under paragraph (b) of this section and the activities under consideration for designation as significant new uses. Such notice may be by telephone, but in this event will be confirmed in writing no later than 30 days after completion of the notice review period.

(3) **Federal Register** documents issued to propose or establish significant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by EPA.

(ii) The premanufacture notice number.

(iii) The CAS number, where available and not claimed confidential.

(iv) A summary of the basis for action under this section.

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of Subpart A of this part applicable to the specific substance and significant new uses.

(vii) If the **Federal Register** document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(4) EPA will issue significant new use rules under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(i)(A) When EPA uses the direct final rulemaking procedure to issue a significant new use rule it will issue a direct final rule in the final rule section of the **Federal Register** following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(B) The **Federal Register** document will state that, unless written notice is received by EPA within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the **Federal Register**, and EPA will issue a proposed rule in the proposed rule section of the **Federal Register**. The proposed rule will establish a 30-day comment period.

(C) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to Subpart E of this part and designating the significant new uses subject to notification.

(ii)(A) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposed rule in the **Federal Register** following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(B) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to Subpart E of this part and designating the significant new uses subject to notification.

(iii)(A) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the **Federal Register** following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(*1*) The significant new use rule will take effect on the date of publication.

(*2*) Persons will be given 30 days from the date of publication to submit comments.

(B) An interim final rule issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the **Federal Register** responding to any written comments received during the 30-day comment period specified in paragraph (d)(4)(iii)(A)(*2*) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(e) *Schedule for issuing significant new use rules.* (1) EPA will issue a proposed rule, an interim final rule, or a

direct final rule within 270 days of receipt of the notice of commencement under § 720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) If EPA receives adverse or critical comments within the designated comment period following publication of a proposed rule or an interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

§ 721.185 Limitation or revocation of certain notification requirements.

(a) *Criteria for modification or revocation.* EPA may at any time modify or revoke significant new use notification requirements for a chemical substance which has been added to Subpart E of this part using the procedures under § 721.160 or § 721.170. Such action may be taken under this section if EPA makes one of the following determinations, unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the substance will not present an unreasonable risk of injury to human health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law for the substance that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received significant new use notices for some or all of the activities designated as significant new uses of the substance and, after reviewing such notices, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data or other information or analysis supporting its decision to add the substance to Subpart E of this part under § 721.170 and has concluded that the substance does not meet the criteria under § 721.170(b).

(5) For a substance added to Subpart E of this part under § 721.160, EPA has examined new information, or has reexamined the test data or other information or analysis supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act, and has concluded that a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act.

(6) For a substance added to Subpart E of this part under § 721.160, certain activities involving the substance have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) *Procedures for limitation or revocation.* Modification or revocation of significant new use notification requirements for a substance that has been added to Subpart E of this part using the procedures described under § 721.160 or § 721.170 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use notification requirements for a substance that has been added to Subpart E of this part using the procedures described in § 721.160 or § 721.170 by writing to the Director of the Office of Toxic Substances and stating the basis for such request. All requests should be sent to the TSCA Document Processing Center (TS-790), Room L-100, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. ATTN: Request to amend significant new use rule. The request must be accompanied by information sufficient to support the request.

(2) The Director of the Office of Toxic Substances will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that substance should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a substance should be limited or revoked, EPA will propose the changes in the **Federal Register**, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

[Approved by the Office of Management and Budget under OMB control number 2070-0012]

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